

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ALL CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**RESPONSES AND OBJECTIONS TO PLAINTIFFS’
“NOTICE TO TAKE VIDEO DEPOSITION OF PATRICIA HOJNOSKI” AND
ACCOMPANYING REQUEST FOR PRODUCTION OF DOCUMENTS**

Defendants Ethicon, Inc. (“Ethicon”) and Johnson & Johnson (“J&J”) (collectively, “Defendants”) hereby respond and object to Plaintiffs’ “Notice to Take Video Deposition of Patricia Hojnoski” (the “Notice”) and Exhibit A to the same. The Notice was filed and served on March 15, 2013, and the deposition of Ms. Hojnoski is scheduled for April 16, 2013. Exhibit A to the Notice is a request for production of documents. Both the Notice and Exhibit A to the Notice are attached hereto as Exhibit 1.

As set forth more fully below, many of the requests for production of documents included in Exhibit A seek documents that Defendants have already produced to Plaintiffs or that have otherwise already been made available to Plaintiffs. Specifically, the documents sought in Request Nos. 1-2 and 5-9 have already been produced to Plaintiffs. Inasmuch as the Notice instructs that Defendants are to produce only those responsive documents that have not already been produced, Defendants do not read Exhibit A as requesting that Defendants replicate their earlier productions or otherwise produce documents that have already been made available for Plaintiff’s review.

The responses and objections contained herein are made without in any way waiving or intending to waive—but on the contrary reserving and intending to reserve—the right at any time to revise, supplement, correct, or add to these objections and responses. Defendants note that no documents have been withheld from production on the basis of the objections set forth in this Response unless expressly stated.

SPECIFIC RESPONSES AND OBJECTIONS TO NOTICE AND EXHIBIT A

Document Request No. 1: All documents relied upon by the deponent in preparing for this deposition.

Responses and Objections to Document Request No. 1: Defendants object that this request seeks information protected by the attorney work product doctrine. *See, e.g., Hickman v. Taylor*, 329 U.S. 495, 511 (1947); *In re Allen*, 106 F.3d 582, 608 (4th Cir. 1997) (observing that “choice and arrangement [of documents in witness’s personnel file by counsel for witness] constitutes opinion work product because [counsel’s] selection and compilation of these particular documents reveals her thought processes and theories regarding this litigation”); *Rhodes v. E.I du Pont de Nemours & Co.*, 558 F. Supp. 2d 660, 671 (S.D. W. Va. 2008) (Goodwin, C.J.) (“Courts acknowledge that the document selection process represents the mental impressions of the party’s counsel and is protected work product.” (internal quotation marks and alterations omitted)). Subject to and without waiving any objection, Defendants note that each and every document relied upon by the deponent in preparing for this deposition has already been produced to Plaintiffs.

Document Request No. 2: All documents concerning corporate, departmental, and employee organizational charts for the Relevant Time Period.

Responses and Objections to Document Request No. 2: Defendants object that this request is overbroad and unduly burdensome, in that it includes no temporal limitation and is not limited in any respect to the products at issue. Without waiving this objection, Defendants have produced organizational charts for Ethicon. These charts were produced at the following Bates ranges:

ETH.MESH.00002221-ETH.MESH.00002548; and

ETH.MESH.00335088-ETH.MESH.00335617.

Defendants note that these organizational charts post-date Ms. Hojnoski's employment at Ethicon.

Document Request No. 3: A copy of the current resume and/or curriculum vitae for Patricia Hojnoski.

Responses and Objections to Document Request No. 3: Defendants note that Plaintiffs are not entitled to the production of a current resume from Ms. Hojnoski, who left Ethicon years ago, pursuant to any Federal Rule of Civil Procedure. However, in the spirit of cooperation, Defendants asked Ms. Hojnoski to provide a copy of her current resume, and she agreed to do so. This document will be provided to Plaintiffs.

Document Request No. 4: A copy of the personnel file and/or employment file for Patricia Hojnoski.

Responses and Objections to Document Request No. 4: Subject to and without waiving any objections, Defendants will produce a redacted version of Ms. Hojnoski's personnel file.

Document Request No. 5: All documents concerning your protocol or standard operating procedures (SOP) for Ethicon, Inc.'s regulatory department applicable to the TVT products for the entire relevant time period, including history of changes and archival versions.

Responses and Objections to Document Request No. 5: Defendants object that this request is overbroad and unduly burdensome. The devices were long term projects, taking a total of more than a dozen years from TVT to TVT Exact and Abbrevio. Thus, the Standard Operating Procedures associated with each device were revised multiple times over the course of this period. Defendants object that this request is dramatically overbroad since there will be numerous standard operating procedures applicable to the regulatory department that have no bearing on this litigation. Additionally, there would be numerous procedures and versions of procedures that would both pre-date and post-date Ms. Hojnoski's term of employment in Ethicon's Regulatory Affairs department.

Subject to and without waiving any objections, in conjunction with the Regulatory Affairs 30(b)(6) deposition, Defendants produced the current versions of the following Standard Operating Procedures: 100083526, Procedure for Establishment Registration and Medical Device Listing; OP608-007, Operating Procedure for 510(k) Pre-market Notification; OP608-008, Operating Procedure for Pre-Market Approval Application Procedure for Medical Devices; OP608-009, Operating Procedure for Annual Reports to FDA for Medical Devices; OP608-010, Operating Procedure for International Affiliates' Medical Device Registration; OP608-011,

Procedure for the Preparation of Technical Files and Design Dossiers; OP608-016, Notification Submission Process for Regulatory Agencies; PR-0000255, Company Procedure for US Regulatory Affairs Review of Promotion and Advertising Material for Medical Devices; PR-0000592, Franchise Procedure for a Global Regulatory Strategy; PS-0000487, Process Steps for Archiving of Regulatory Affairs Vital Records-Paper; PS-0000560, Franchise Guidance Document for Assessing Impact of Change to PMA Products and BLA Products; PR-0011368, Regulatory Impact Assessment Process in the ADAPTIV System. Defendants further state that they have produced regulatory SOPs in Productions 36, 40, 55, 70, 90 and 93. They bear Bates numbers:

ETH.MESH.03667696 - ETH.MESH.03667704

ETH.MESH.03745130 - ETH.MESH.03745136

ETH.MESH.04315779 - ETH.MESH.04315785

ETH.MESH.04938882 - ETH.MESH.04938890

ETH.MESH.05141146 - ETH.MESH.05141158

ETH.MESH.05436917 - ETH.MESH.05436928

ETH.MESH.06024964 - ETH.MESH.06024970

ETH.MESH.06025073 - ETH.MESH.06020577

ETH.MESH.06391427 - ETH.MESH.06391459

Defendants note that the parties are continuing to engage in the meet and confer process to determine whether there are additional documents that are relevant and responsive to this Request.

Document Request No. 6: All documents that index or catalog Defendants' approved or draft advertising, sales and marketing materials, and print and broadcast advertisements, sales aids, visuals, sales scripts, sales guides, and reminder pieces relating to TVT products.

Responses and Objections to Document Request No. 6: Defendants object that this request is vague and ambiguous, overbroad, and unduly burdensome. By its terms, the request seeks the production of materials that pre-date and post-date Ms. Hojnoski's term of employment and for products that Ms. Hojnoski never worked on. Such information is not designed to lead to the discovery of admissible evidence. Defendants further object to the extent that this request seeks responsive materials used in any country outside of the United States. Consistent with the ongoing meet and confer between the parties, Defendants are willing to produce a subset of such materials that represent a reasonable compromise on this issue, but the parties are still negotiating on this point. Subject to and without waiving any objections, Defendants have produced documents responsive to this request. *See* custodial file productions for Daharini Amin, Lisette Caro-Rosado, Katie Cheng, Susie Chilcoat, Lynn Hall, Jason Hernandez, Piet Hinoul, Scott Jones, Aaron Kirkemo, Susan Lin, Linda Linton, Bryan Lisa, Brian Luscombe, Kevin Mahar, Jonathan Meek, Melissa Muguruza, Pat Napoda, Mary O'Connell, Robin Osman, Ken Pagel, Paul Parisi, Bart Pattyson, David Robinson, Laura Vellucci, Martin Weisberg; *see also* Copy Review Paper Files Prods. 3, 4, 7, 22, 70 and 90; *see also* Copy Review Indexes that were provided to plaintiffs' counsel in the Consolidated New Jersey Litigation on February 3, 2012 and April 10, 2012; and Index of TVT Patient Brochures produced to Plaintiffs on March 11, 2013, in these proceedings.

Document Request No. 7: All documents relating to, submitted to, created by, or concerning any committee or group that reviews and approves any labeling, packaging, advertising, sales and marketing materials, or external communications relating to TVT products.

Responses and Objections to Document Request No. 7: Subject to and without waiving any objections, Defendants state that the documents responsive to this request have been produced to Plaintiffs. *See* custodial file productions for Daharini Amin, Axel Arnaud, Lisette Caro-Rosado, Judi Gauld, Evelyn Hall, Matt Henderson, Jason Hernandez, Joseph Herron, Scott Jones, Marianne Kaminski, Aaron Kirkemo, Susan Lin, Linda Linton, Brian Luscombe, Kevin Mahar, Melissa Muguruza, Robin Osman, Jennifer Paradise, Paul Parisi, Bart Pattyson, David Robinson, Dan Smith, Donna Taggert, Martin Weisberg; *see also* Copy Review Paper Files, Prods. 3, 4, 7, 14, 22, 32, 39, 70 and 90, Sales and Marketing\Lynn Hall\TVT Groupshare, Prod. 14.

Document Request No. 8: All documents relating to any FDA 522 Orders for TVT products.

Responses and Objections to Document Request No. 8: Subject to and without waiving any objections, Defendants state that all documents responsive to this request have been produced to Plaintiffs. *See* custodial file productions for Tom Affeld, Laura Angelini, Catherine Beath, Lesley Fronio, Judi Gauld, Piet Hinoul, Brian Kanerviko, Martin Madden, Iris Magalhaes, Pat Napoda, Lucy Paterson, Laura Vellucci; *see also* EWHU Regulatory SharePoint, Prods. 33 and 61, RDEWHU SharePoint, Prod. 90, Regulatory Affairs\522 Orders Group Share, Prods 61 and 95; Susan Lin custodial file and Regulatory Affairs Group Shares, Prod. 96.

Document Request No. 9: All documents relating to Ethicon's decision to cease commercialization of or withdraw from market any TVT products.

Responses and Objections to Document Request No. 9: Subject to and without waiving any objections, Defendants state that all documents responsive to this request have been produced to Plaintiffs. *See* custodial file productions for Daharini Amin, Laura Angleini, Axel Arnaud, Kelly Arnold, Boris Batlke, Catherine Beath, Scott Ciarrocca, Melissa Day, Paul DeCosta, James Flint, Kevin Frost, Judi Gauld, Dimpy Gupta, Matt Henderson, Piet Hinoul, Matt Johnson, Scott Jones, Brian Kanerviko, Dan Lamont, Brian Luscombe, Iris Magalhaes, Pat Napoda, David Overaker, Jennifer Paradise, Paul Parisi, Lucy Paterson, Adrian Roji, Elizabeth Vailhe, Laura Vellucci, Frank Yasunas, Vincenza Zaddem; *see also* EWHU Regulatory SharePoint, Prods. 33 and 61; Susan Lin custodial file and Regulatory Affairs Group Shares, Prod. 96.

Respectfully submitted,

ETHICON, INC. AND
JOHNSON & JOHNSON

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CERTIFICATE OF SERVICE

I, David B. Thomas, certify that on March 27, 2013, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ David B. Thomas

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